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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/675,852

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Jacqueline E. Heard

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1145

47550

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02/25/2009

MENDEL BIOTECHNOLOGY C/O MOFO SF  
425 MARKET STREET  
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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/675,852	HEARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008 and 18 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-42, 45-51, 54-58 and 61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-42, 45-51, 54-58 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/26/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the claims amendment filed 18 November 2008 and the Remarks filed 15 September 2008.
2. The rejection under 35 U.S.C. § 102(e) as being anticipated by da Costa e Silva *et al* (U.S. Patent 6,677,504) is withdrawn in view of Applicants' amendments to the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

4. Applicants' remarks concerning their claim of priority are noted on page 6 of the Remarks. The Examiner notes that the limitations in instant claim 40 are found on page 46 not page 40 of the instant specification.

In view of Applicants' amendments to the claims and Applicants' evidence, the instant claims are given the following priority dates for the purposes of applying the prior art;

Claims 39, 45-48, 54-56 and 61 are given the priority date of 17 November 1999, the filing date of U.S. Provisional Application 60/166,228,

Claims 40-42, 49-51, 57 and 58 are given the priority date of 30 September 2003, the instant application.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 39-42, 45-51, 54-58 and 61 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 14 April 2008.

Applicant's arguments filed 15 September 2008 have been fully considered but they are not persuasive.

Applicants argue that in the case of the present specification, the skilled artisan would, upon reading the present application, understand that Applicants were in possession of the claimed invention in light of the extensive disclosure of a significant number of sequences included within the scope of the claims, and both the conventional and well-known methods, as well as the methods presently disclosed, of identifying related polypeptides, including CCAAT-binding transcription factors, and testing these sequences in plants. Applicants argue that it would thus have been made clear to said skilled artisan that Applicants were in possession of the invention at the time the present application was filed (page 7, 4<sup>th</sup> paragraph of the Remarks).

Applicants argue that contrary to the assertions provided in the Office action, one of skill in the art could readily envision each of the polynucleotide sequences that hybridize to SEQ ID NO: 3 based on the hybridization analysis being claimed.

Applicants argue that the specification contains an unambiguous description of the

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structure of any member of the claimed genus by reciting the conditions required for hybridization to a canonical sequence, SEQ ID NO: 3 (page 7, 5<sup>th</sup> paragraph of the Remarks). These arguments are not found to be persuasive. CCAAT-binding transcription factors regulate the expression of a wide variety of genes that are involved in a wide variety of phenotypes, other than tolerance to salt. There is no indication in the instant specification that the genus of recombinant polynucleotides that would hybridize under the claimed conditions would confer on a transgenic plant increased tolerance to salt than a control plant as broadly claimed. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424, 1433 (DC WNY 2003) which teaches knowing the "starting point" is not enough; that is little more than a research plan.

Applicants' arguments concerning Example 6 of the Training materials on pages 7-8 of the Remarks are not found to be persuasive because a tyrosine kinase enzyme is not equivalent to the CCAAT-binding transcription factor of the instant claims. The evidence in Table 6 (page 95 of the instant specification) shows that the G482 polypeptide confers heat tolerance when overexpressed in a plant, whereas the G481 polypeptide does not but does confer drought tolerance. The G485 and G3395 polypeptides do not confer either heat tolerance or drought tolerance to a transgenic plant but tolerance to high salt. In addition, the type of tolerance conferred by the G481 polypeptide appears to be relative to the promoter used. Hence, the conservation of structure is not necessarily an indication for conservation of function in the instant case.

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7. Claims 39-42, 45-51, 54-58 and 61 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of making and a transgenic plant made, comprising a recombinant polynucleotide encoding a polypeptide of SEQ ID NO: 4 that exhibits increased germination when grown on high salt or mannitol containing medium and increased heat tolerance, does not reasonably provide enablement for methods of making and transgenic plants made comprising other recombinant polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 14 April 2008. Applicant's arguments filed 15 September 2008 have been fully considered but they are not persuasive.

Applicants argue that methods for identifying related sequences and determining their function, in this case the ability to confer greater salt tolerance to plants, are provided in the specification. Applicants argue that these methods, at the time of the instant filing, were known in the art, and the level of skill in the art was high. Applicants argue that even if a large amount of experimentation is required, said amount is permitted if it is routine (page 9, 2<sup>nd</sup> paragraph of the Remarks).

Applicants argue that the methods provided in the specification and known in the art are routine, and the practice of identifying functional species of the claims and testing them in plants is a matter of routine, as Applicants have demonstrated.

Applicants argue that the present application describes four related CCAAT-binding

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transcription factors, G481, G482, G485 and G3395, that were each shown to be more tolerant to high salt (page 90 at line 21, page 92 at line 7, page 93 line 24, and page 94 line 27, respectively). Applicants argue that, based on this disclosure and the knowledge in the art, Applicants submit that the skilled artisan would not find it unduly burdensome to identify function species of the claims (page 9, 3<sup>rd</sup> paragraph of the Remarks). These arguments are not found to be persuasive for the reasons of record. It is unclear which of the other three asserted species would meet the limitations of the instant claims, i.e. hybridizing to SEQ ID NO: 3. Applicants have argued that the fact that a sequence is expressed in response to an general, as is presently the case, or even a specific environmental influence is not an indication that it will confer tolerance to a specific stress when it is overexpressed. Thus [one] skilled in the art understand that 100s of sequences may be up- or down-regulated in response to an environmental influence. It was recognized in Swindell et al. (2007) "The biological limitations of transcriptomics in elucidating stress and stress responses." *Heredity* 99: 143-150, that "[c]andidate genes *with a well-supported role in stress-response pathways* provide good prospects for subsequent experimental study" (*emphasis added*; page 149, left column), but "[t]he identification of temperature-related genes [i.e., regulated in response to environmental changes] through microarray analysis represents *only a first step* towards understanding their role in cold- and heat-stress- regulatory *pathways*"(*emphasis added*; page 149, left column). See also Feder et al. (2005) *J. Evol. Biol.* 18: 901-910; "[p]ublished work to date suggests that mRNA abundance typically provides little information on protein activity and fitness and *cannot substitute for detailed functional*

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*and ecological analyses of candidate genes"* (*emphasis added*; Abstract). Thus, even today, the skilled artisan would not be inclined to attempt to overexpress each individual sequence determined to respond to an environmental stress to determine if they can be used to produce *tolerance* to a stress (paragraph spanning pages 9-10 of the Remarks in response to the rejection under 35 U.S.C. 103(a)). The Examiner concurs with Applicants' assessment of the relative skill of those in the art and the unpredictability of the instant art and the nature of the invention. Whether a plant transcription factor, when overexpressed in a transgenic plant, will give a specific phenotype is highly unpredictable, and as Applicants' have show such a phenotype may be dependent upon which promoter one would use.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 39-42, 45-51, 54-58 and 61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards *et al* (July 1998, Plant Physiology 117: 1015-1022) in view of Harada *et al* (U.S. Patent 6,235,975 B1, filed 24 June 1998). This rejection is repeated for the reason of record as set forth in the last Office action mailed 14 April 2008. Applicant's arguments filed 15 September 2008 have been fully considered but they are not persuasive.



Applicants argue that the fact that Edwards et al. recognized that "further research is required to understand the regulation of these factors" indicates that Edwards et al. were aware that they had not provided a completed understanding of the "characteristic of abiotic stress tolerance that would have naturally flown from the use of the AtHAP3b CAAT-box transcription factor[s]" (Office action). Applicants argue that although finding the claimed salt tolerant plants is a matter of routine, Applicants have discovered that lines transformed with G482 and phylogenetically-related sequences do not *necessarily* have increased tolerance to salt stress. See, for example, the specification at page 94, lines 26-27: "[o]ne of the lines of G3395 overexpressors tested was found to be more tolerant to high salt levels", or Table 6, showing that the lines produced with G482 and the two- component supertransformation approach were not more salt tolerant (at least some lines with a direct fusion approach were) whereas G481-overexpressing lines produced with a superactivation approach were more tolerant to salt but direct fusion lines were not (at the time of filing) (page 10, 2<sup>nd</sup> paragraph of the Remarks).

Applicants argue that in order for an inherent quality to qualify as an element sufficient to anticipate a claimed element that inherent quality must necessarily and inevitably follow from the teaching. Applicants argue that the Federal Circuit carefully distinguished between an accidental anticipation and inherent anticipation in the decision in Schering Corp. v. Geneva Pharms, Inc., 339 F.3d 1373 (2003). Applicants argue that the court referred to prior case law where the Supreme Court had held that accidental inherency was not sufficient for inherent anticipation: "In Eibel, the Court

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found no evidence of the claimed subject matter in the prior art. Eibel, 261 U.S. at 66 ('We find no evidence that any pitch of the wire..., had brought about such a result., and..., if it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation.')." Applicants argue that whereas the Federal Circuit held that, "[i]n the context of accidental anticipation, DCL is not formed accidentally or under unusual conditions when loratadine is ingested. The record shows that DCL *necessarily and inevitably* forms from loratadine under normal conditions. DCL is a necessary consequence of administering loratadine to patients" (*emphasis added*). See Schering at 1378. T Applicants argue that the fact that the G482 overexpression may produce increased tolerance to salt is not sufficient to anticipate by inherency the present claims to plants (paragraph spanning pages 10-11 of the Remarks).

These arguments are not found to be persuasive. The prior art had taught that it was obvious to operably link a CaMV 35S promoter to a CCAAT-binding transcription factor coding region and transform a plant therewith (Harada, claim 7). In response to applicant's argument that the transgenic plants have increased salt tolerance, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). One cannot separate the function of the AtHAP3b transcription factor taught by Edwards from its structure. What Applicants assert as being unexpected would have been the most obvious combination (a transgenic plant) using

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the subcombination (a recombinant polynucleotide encoding the AtHAP3b transcription factor) as taught by Edwards, operably linked to the CaMV 35S constitutive promoter.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 39-42, 45-51, 54-58 and 61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 73 of copending Application No. 11/069,255 for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants arguments are noted (page 11 of the Remarks), but as the instant claims are not yet deemed allowable the instant rejection is maintained.

***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/  
Primary Examiner, Art Unit 1638  
18 February 2009